KalVista Pharmaceuticals Provides Operational Update and Fiscal Year Financial Results

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– Sebetralstat Phase 3 KONFIDENT and KVD824 Phase 2 KOMPLETE Clinical Trial Enrollment on Track –

– Formal Notification Received of Sebetralstat EU Orphan Drug Status –

CAMBRIDGE, Mass. & SALISBURY, England--(BUSINESS WIRE)--Jul. 7, 2022-- KalVista Pharmaceuticals, Inc. (NASDAQ: KALV), a clinical stage pharmaceutical company focused on the discovery, development, and commercialization of oral, small molecule protease inhibitors, today provided an operational update and released financial results for the fiscal year ended April 30, 2022.

"We are pleased with the progress we have made over the last fiscal year in the development of the candidates in our oral hereditary angioedema franchise," said Andrew Crockett, Chief Executive Officer of KalVista. "We are meeting our enrollment targets for both our current clinical trials, the sebetralstat KONFIDENT Phase 3 and KVD824 KOMPLETE Phase 2. In addition, we are making great strides in developing our next wave of investigational compounds with promising preclinical data for our oral Factor XIIa inhibitor program. The Company is also well-capitalized, with funding until at least early 2024, which we expect takes us beyond data from both of our ongoing clinical trials."

Fiscal 2022 and Recent Business Highlights:

- In June 2022, the Company received formal notice that the European Commission has designated sebetralstat as an orphan medicinal product for the treatment of hereditary angioedema. The orphan designation allows KalVista guaranteed access to the centralized procedure for marketing authorization, among other benefits, and would provide 10 years of market exclusivity.
- Enrollment is proceeding as expected for the Phase 3 KONFIDENT trial for sebetralstat, with data expected in the second half of 2023. The Phase 2 KOMPLETE clinical trial for KVD824, an oral plasma kallikrein inhibitor KalVista is developing for the prevention of HAE attacks, also remains on track with its enrollment targets. Data from the KOMPLETE trial is expected in mid-2023.
- Reported promising preclinical data for our oral factor XIIa inhibitor program at the KININ2022 conference. Presentations showed that our oral FXIIa inhibitors block the initiation and amplification of the kallikrein kinin system (KKS) in preclinical models as well as suppressing FXII zymogen enzyme activity.
- Announced the appointment of Patrick A. Treanor, Chief Operating Officer of Pathalys Pharma, to the Board of Directors.
- Announced that the name "sebetralstat" was approved by the World Health Organization's International Nonproprietary Names (WHO-INN) Expert Committee and the American Medical Association's United States Adopted Names (AMA-USAN) Council for the drug candidate formerly known as KVD900.
- Published new data for sebetralstat in the journal *Clinical & Experimental Allergy.* In the publication, orally administered sebetralstat was shown to be quickly absorbed and provided rapid and near-complete inhibition of plasma kallikrein and strong suppression of kallikrein-kinin system activation in patients with HAE.
- Announced the initiation of the Phase 3 KONFIDENT clinical trial evaluating the efficacy and safety of sebetralstat as the first potential oral, on-demand therapy for hereditary angioedema (HAE) attacks. The worldwide, double-blind, placebo-controlled crossover trial will evaluate the efficacy of two dose levels of sebetralstat compared to placebo in adolescents and adults experiencing acute HAE attacks.
- Provided new data from the Phase 2 trial of sebetralstat at the American Academy of Allergy, Asthma & Immunology (AAAAI) Annual Scientific Meeting. Data presentations highlighted rapid suppression of plasma kallikrein activity after sebetralstat administration and its relationship with symptomatic relief from HAE attacks.

Fourth Quarter and Full Year Financial Results:

- Revenue: No revenue was recognized for the three months and fiscal years ended April 30, 2022, or April 30, 2021, respectively.
- R&D Expenses: Research and development expenses were $19.2 million for the three months ended April 30, 2022, compared to $11.9 million for the same period in the prior fiscal year. Research and development expenses were $70.2 million for the fiscal year ended April 30, 2022, compared to $41.3 million for the prior fiscal year. The increase in spending in the fiscal year ended April 30, 2022, primarily reflects increased costs related to the ongoing clinical trials for sebetralstat and KVD824, increased preclinical spending, and a headcount driven increase in personnel costs.
- G&A Expenses: General and administrative expenses were $7.6 million for the three months ended April 30, 2022, compared to $6.2 million for the same period in the prior fiscal year. General and administrative expenses were $26.4 million for the fiscal year ended April 30, 2022, compared to $16.6 million for the prior fiscal year. The increase in G&A expenses was primarily due to an increase in compensation related expenses and to a lesser extent, increases in professional fees, commercial planning expenses, facility costs and other administrative costs.
- Net Loss: Net loss was $24.1 million, or $(0.98) per weighted average basic and diluted share, for the three months ended April 30, 2022, compared to net loss of $15.0 million, or $(0.65) per weighted average basic and diluted share for the same

period in the prior fiscal year. Net loss was $82.3 million, or $(3.36) per weighted average basic and diluted share for the fiscal year ended April 30, 2022, compared to net loss of $46.2 million, or $(2.42) per weighted average basic and diluted share in the prior fiscal year. The increase in net loss and net loss per share primarily resulted from the increase in operating expenses, primarily research and development.

- Cash position: Cash, cash equivalents and marketable securities were $166.2 million on April 30, 2022, compared to $248.9 million on April 30, 2021. The decrease in the net cash position over the fiscal year is primarily due to increased operating expenses.

About KalVista Pharmaceuticals, Inc.

KalVista Pharmaceuticals, Inc. is a pharmaceutical company focused on the discovery, development, and commercialization of oral, small molecule protease inhibitors for diseases with significant unmet need. KalVista has developed a proprietary portfolio of novel, small molecule plasma kallikrein inhibitors initially targeting hereditary angioedema (HAE) and diabetic macular edema (DME). KalVista is developing sebetralstat as an oral on-demand therapy for acute HAE attacks and is enrolling the Phase 3 KONFIDENT clinical trial. KVD824 is in development for prophylactic treatment of HAE, with the Phase 2 KOMPLETE clinical trial underway. In addition, KalVista's oral Factor XIIa inhibitor program represents a new generation of therapies that may further improve the treatment of HAE for patients. In DME, an intravitreally administered plasma kallikrein inhibitor, called KVD001, has completed a Phase 2 clinical trial.

For more information about KalVista, please visit www.kalvista.com.
For more information on the sebetralstat HAE on-demand Phase 3 KONFIDENT study, please visit www.konfidentstudy.com.
For more information on the KVD824 HAE prophylaxis Phase 2 KOMPLETE study, please visit www.kompletestudy.com.

Forward-Looking Statements

This press release contains "forward-looking" statements within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as: "anticipate," "intend," "plan," "goal," "seek," "believe," "project," "estimate," "expect," "strategy," "future," "likely," "may," "should," "will" and similar references to future periods. These statements are subject to numerous risks and uncertainties, including the potential impact of COVID-19, that could cause actual results to differ materially from what we expect. Examples of forward-looking statements include, among others, timing or outcomes of communications with the FDA, our expectations about safety and efficacy of our product candidates and timing of clinical trials and its results, our ability to commence clinical studies or complete ongoing clinical studies, including our Phase 3 KONFIDENT and Phase 2 KOMPLETE clinical trials, and to obtain regulatory approvals for sebetralstat, KVD824 and other candidates in development, the ability of sebetralstat, KVD824 and other candidates in development to treat HAE or DME, and the future progress and potential success of our oral Factor XIIa program. Further information on potential risk factors that could affect our business and financial results are detailed in our filings with the Securities and Exchange Commission, including in our annual report on Form 10-K for the year ended April 30, 2021, our quarterly reports on Form 10-Q, and our other reports that we may make from time to time with the Securities and Exchange Commission. We undertake no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

KalVista Pharmaceuticals Inc.
Condensed Consolidated Balance Sheets
(in thousands, except share and per share amounts)
(Unaudited)

	April 30, 2022	April 30, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 30,732	$ 50,592
Marketable securities	135,470	198,337
Research and development tax credit receivable	14,098	10,418
Prepaid expenses and other current assets	13,347	4,917
Total current assets	193,647	264,264
Property and equipment, net	2,178	1,791
Right of use assets	7,862	5,758
Other assets	193	200
Total assets	**$ 203,880**	**$ 272,013**
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,638	$ 1,981
Accrued expenses	6,961	6,930
Lease liability - current portion	977	863
Total current liabilities	11,576	9,774
Long-term liabilities:		
Lease liability - net of current portion	7,211	5,046
Total long-term liabilities	7,211	5,046
Stockholders' equity:		
Common stock, $0.001 par value	25	24
Additional paid-in capital	439,104	426,437
Accumulated deficit	(250,175)	(167,836)
Accumulated other comprehensive loss	(3,861)	(1,432)
Total stockholders' equity	185,093	257,193

Total liabilities and stockholders' equity	**$ 203,880**	**$ 272,013**

KalVista Pharmaceuticals Inc.
Condensed Consolidated Statement of Operations
(in thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended April 30,		Years Ended April 30,	
	2022	**2021**	**2022**	**2021**
Revenue	**$ -**	**$ -**	**$ -**	**$ -**
Operating expenses:				
Research and development	19,213	11,877	70,167	41,286
General and administrative	7,598	6,165	26,446	16,637
Total operating expenses	26,811	18,042	96,613	57,923
Operating loss	**(26,811)**	**(18,042)**	**(96,613)**	**(57,923)**
Other income:				
Interest income	268	314	1,090	903
Foreign currency exchange rate gain (loss)	(1,008)	132	(1,537)	847
Other income	3,438	2,639	14,721	9,929
Total other income	**2,698**	**3,085**	**14,274**	**11,679**
Loss before income taxes	(24,113)	(14,957)	(82,339)	(46,244)
Income tax (benefit) expense	-	-	-	-
Net loss	**$ (24,113)**	**$ (14,957)**	**$ (82,339)**	**$ (46,244)**
Net loss per share, basic and diluted	**$ (0.98)**	**$ (0.65)**	**$ (3.36)**	**$ (2.42)**
Weighted average common shares outstanding, basic and diluted	24,545,360	23,118,127	24,473,092	19,094,440

KalVista Pharmaceuticals Inc.
Condensed Consolidated Statements of Cash Flows
(in thousands, unaudited)

	Years Ended April 30,	
	2022	**2021**
Cash flows from operating activities		
Net loss	$ (82,339)	$ (46,244)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	564	537
Stock-based compensation expense	11,086	7,118
Realized (gain) loss from sale of marketable securities	581	(153)
Non-cash operating lease expense	179	114
Amortization of premium on available for sale securities	2,565	685
Foreign currency exchange (gain) loss	1,552	(574)
Changes in operating assets and liabilities:		
Research and development tax credit receivable	(5,201)	7,457
Prepaid expenses and other current assets	(9,280)	(244)
Accounts payable	1,687	150
Accrued expenses	472	983
Net cash used in operating activities	(78,134)	(30,171)
Cash flows from investing activities		
Purchases of available for sale securities	(136,920)	(201,210)
Sales and maturities of available for sale securities	195,711	53,638
Acquisition of property and equipment	(931)	(82)
Net cash provided by (used in) investing activities	57,860	(147,654)
Cash flows from financing activities		
Issuance of common stock, net of offering expenses	-	210,582
Issuance of common stock from equity incentive plans	1,581	1,535

Net cash provided by financing activities	1,581	212,117
Effect of exchange rate changes on cash and cash equivalents	(1,167)	511
Net increase (decrease) in cash and cash equivalents	(19,860)	34,803
Cash and cash equivalents, beginning of year	50,592	15,789
Cash and cash equivalents, end of year	$ 30,732	$ 50,592

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